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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/728,207	12/01/2000	Yoshiyuki Nagai	50026/005002	4421

31496 7590 07/14/2003

SMITH PATENT CONSULTING CONSULTING, LLC  
P.O. BOX 2726  
ALEXANDRIA, VA 22301

EXAMINER
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MOSHER, MARY

ART UNIT	PAPER NUMBER
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1648

DATE MAILED: 07/14/2003

19

Please find below and/or attached an Office communication concerning this application or proceeding.

**Advisory Action**

Application No.

09/728,207

Applicant(s)

Nagai et al

Examiner

Mosher

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 4/18/03 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

Therefore, further action by the applicant is required to avoid the abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

THE PERIOD FOR REPLY [check only a) or b)]

- a) ☐ The period for reply expires \_\_\_\_\_ months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☒ A Notice of Appeal was filed on 4/18/03. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☒ The proposed amendment(s) will not be entered because:
- (a) ☒ they raise new issues that would require further consideration and/or search (see NOTE below);
- (b) ☐ they raise the issue of new matter (see NOTE below);
- (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: See attachment.

3. ☐ Applicant's reply has overcome the following rejection(s):

4. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because:  
See attachment.

6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.

7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☒ will not be entered or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: \_\_\_\_\_

Claim(s) objected to: \_\_\_\_\_

Claim(s) rejected: 1-13

Claim(s) withdrawn from consideration: \_\_\_\_\_

8. ☐ The proposed drawing correction filed on \_\_\_\_\_ is a) ☐ approved or b) ☐ disapproved by the Examiner.

9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_

10. ☒ Other: Interview Summary

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### **DETAILED ACTION**

The amendment filed April 18, 2003 would obviate the at least the 112 2nd issues.

However, broadening the scope to any Sendai vector containing a foreign gene, or to any Sendai virus with modified NP, P, or L, would require additional search and consideration of non-"disseminative" embodiments that were previously excluded from the claimed subject matter.

Also, entry of the amendment would require consideration of the new issue of the effective date of claims as amended, and require consideration of new double patenting issues for copending applications with claims directed to Sendai "lacking disseminative capability".

#### ***Double Patenting***

Applicant argues that the provisional double patenting rejections are improper because the other applications were filed later than this application, citing MPEP 706.02(k). However, these are double patenting rejections, not rejections based on prior art under 35 US 102(e). The relevant citation is MPEP 804. Applicant is correct in arguing that the later filed applications are not available as prior art, that is why the provisional double patenting rejections were not accompanied by provisional rejections under 35 USC 102(e) or 35 USC 103. Applicant argues that submission of a terminal disclaimer is only appropriate when the earlier filed applications have matured to a patent. If the only rejections remaining in an application are those of provisional double patenting, it is proper to withdraw the provisional rejection(s) in the first application to issue, and maintain the rejection(s) in applications issuing later. However, there are other rejections remaining in this application, therefore the provisional rejections are maintained until all

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other issues are resolved. Meanwhile, copending application 09/436,504 has matured to a patent, therefore the obviousness-type double patenting rejection is no longer provisional.

Applicant argues that 09/436,504 is not commonly assigned and cannot be avoided through the filing of a terminal disclaimer. However, there is a common inventor, and the claimed subject matter is not patentably distinct from the claims in the other application (now a patent), therefore the obviousness-type double patenting rejection is proper. The instant claimed invention broadly drawn to recombinant Sendai virus encoding a foreign gene, methods of producing protein, and allantoic fluid containing the virus and expressed protein, is not patentably distinct from the previously patented claims more narrowly drawn to an egg containing a recombinant Sendai virus encoding a cytokine, the chorioallantoic fluid, and process of producing the cytokine. In this case, one of ordinary skill in the art would have seen the generic claims involving "foreign gene" as obvious over the species claims "cytokine" since a cytokine would have been instantly recognizable as a gene foreign to Sendai virus, and use of any foreign gene in a vector suggests use of many other foreign genes to those of ordinary skill in the vector art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary E. Mosher, Ph.D. whose telephone number is (703) 308-2926. The examiner can normally be reached on Monday -Thursday and alternate Fridays from 6:30 AM to 4:00 PM.

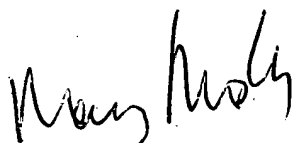
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached on (703) 308-4027. The fax phone numbers for this Group are now

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(703) 872-9306 for Before Final responses, and (703) 872-9307 for After Final responses. Faxes for this Group can also be sent to (708) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

July 9, 2003

  
MARY E. MOSHER  
PRIMARY EXAMINER  
GROUP 1800 1600